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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,302	11/21/2005	Stephan Schwers	2002P56022US	6176

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SIEMENS CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER	
ZEMAN, MARY K	
ART UNIT	PAPER NUMBER
1631	
MAIL DATE	DELIVERY MODE
03/23/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,302	SCHWERS ET AL.	
	Examiner	Art Unit	
	Mary K. Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *63 and 65-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *63 and 65-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/8/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/8/09 has been entered.

The petition for a three month extension was granted, and expired 3/8/10. The submission of the IDS filed with the RCE has been entered and considered. No specific arguments relating to this submission or the Final Rejection are of record.

Claims 63, and 65-70 are pending in this application. All other claims have been canceled.

Applicant's arguments and amendments filed 3/5/09 have been fully considered but they are not completely persuasive. Rejections not repeated below have been withdrawn..

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 63 and 65-70 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has amended independent claim 63 to set forth a step of binding a probe to a polymorphic site of a gene of interest and genotyping for one of 3 particular SNP's. Applicant's

arguments regarding this rejection have been fully considered, but are not persuasive. The binding step does not actually require that the probe be one of the 3 particular SNP sites, and the claim still does not recite that the genotype information for the control and risk groups are obtained from any source. The claim does not set forth identifying proper related control group, nor does it set forth genotyping that control group. The equations of the claim further require a group known to have or be at risk for the named disease, however there is no way to obtain that information. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Further, the claim is drawn to methods of determining a risk for developing Cardiovascular disease (CVD). Cardiovascular disease is a complex disease which involves many systems of the body and multiple chemical and biochemical pathways. CVD is not a single gene disease, and its multifactorial nature has been under study for many years. (Ross, 1993; Lusis, 2000; PTO-1449) As set forth in the specification it covers diseases from congestive heart failure, myocardial infarction, coronary artery disease, all kinds of arrhythmias, and vascular diseases. A variety of genetic polymorphisms have been studied for their use in treating or predicting CVD with varying success. (for example, Pedro-Botet, 2000; Basso et al., 2002: PTO-1449). The recited SNP's are not known to be associated with any or all these disease processes, nor has the specification shown a diagnostic link for these SNPs for all patient groups. The SNP's are alleged to be related to the ATP Cassette Binding Transporter 1, and two variants thereof. The specification does not identify how this gene is known to be related to CVD, nor what aspect of CVD this gene may be involved in. The generic disclosure of the functions of the

ABC1 superfamily fail to associate this gene with CVD, nor does it explain how this gene is involved in any symptom, sign or disease process of this disease. The specification does not provide any evidence that these particular SNPs have diagnostic power in any population. It does not show the testing of said SNPs in individuals who then either do or do not subsequently develop CVD. It is not set forth that the calculation of risk set forth in the specification actually leads to diagnosis of a patient who eventually develops any aspect of CVD. It does not set forth evidence that any particular genotype is actually protective for any individual to inhibit the development of any aspect of CVD. As such this is an invitation to experiment with patient groups, control groups, and individual genomes to determine whether the recited SNP's have any value in a risk calculation as set forth in the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 63 and 65-70 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to methods of calculating a single patient's risk of developing CVD. However, the steps of claim 63 do not provide for inputting the actual patient's information into the recited risk calculation. The claim sets forth N 11-13, which are for a "population of patients being tested" and N21-23, which are for information from a "population of patients known not to be at risk". The claim does not set forth obtaining the control information, nor the known risk population. Further, it is unclear that the probe being used to bind the gene of interest is in any way related to the SNP being genotyped in the next step. It would appear the claim is lacking essential method steps for performing the task set forth in the preamble.

Conclusion

This is a RCE of applicant's earlier Application No. 10524302. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjie Moran can be reached on (571) 272 0720. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Mary K Zeman/
Primary Examiner, Art Unit 1631